Date _____ Analyst _____

Dissolution Apparatus: Manufacturer _____ Model #_____ Serial #_____ Glass Dissolution Vessels: Manufacturer _____

MECHANICAL CALIBRATION REPORT SHEET -- APPARATUS 1 (BASKET)

Calibration Parameter	Point of Measurement	Results & Comments	Tools Used	DPA Tolerances
Vessel dimensions (Inspect at time of receipt only)	See USP		Caliper, ruler	See USP
Basket dimensions (Inspect at time of receipt only)	See USP		Caliper, ruler	See USP
Basket examination (Examine at time of use)				No gross defects as determined by visual inspection
Visual inspection of belts, check ball bearings, oil bearings and rollers				Belts are tight, clean, free of cracks, properly aligned, shafts turn freely
Shaft wobble	2 cm above top of basket	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	Runout gauge	$\leq$ 0.5 mm total runout
Basket wobble	Bottom of basket rim	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	Runout gauge	$\leq$ 1.0 mm total runout
Shaft verticality	Above vessel	Record results at 2 points that are 90° apart. Bubble is centered within lines at the following positions: (Y/N) Shaft1 Pt1:_____ Pt2:_____ Shaft4 Pt1:_____ Pt2:_____ Shaft2 Pt1:_____ Pt2:_____ Shaft5 Pt1:_____ Pt2:_____ Shaft3 Pt1:_____ Pt2:_____ Shaft6 Pt1:_____ Pt2:_____	Bubble level	Bubble centered within the lines of a bubble level
Vessel/Shaft centering and vessel verticality	Setp 1: A Distek CenterChek 1.5 mm above basket. Step 2: Move CenterChek 60 mm above basket. Note: Basket bottom 2.5 cm above vessel bottom	Step 1: CenterChek 1.5 mm above basket 1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ Step 2: CenterChek 60 mm above basket 1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	Distek CenterChek	1 mm from centerline
Height check/Basket Depth	Basket Bottom	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	Distek HeightChek	25 $\pm$ 2 mm
Vibration	Basket shafts, baseplate		None	No significant vibration (tolerance may be changed upon further vibration studies)
Rotational speed		50 rpm _____ 100 rpm _____	Digital optical tachometer	$\pm$ 2 rpm
Vessel temperature (Measured at time of use)		1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	Mercury thermometer	37 $\pm$ 0.5° C